

**REMARKS**

Claims 1, 3, 5-13, 15-20, 22-28, and 37-43 are pending in this application. Non-elected claims 5-7, 10-13, and 22-27 have been withdrawn from consideration by the Examiner. By this Amendment, claims 1, 3, 8, 9, 15, 20, 28, and 37 are amended, claims 2, 4, 14, 21, and 29-36 are canceled, and claims 38-43 are added. Support for the amendments to the claims and new claims 38-43 may be found, for example, in the specification at page 3, line 26 to page 4, line 7 and page 6, line 30 to page 7, line 9, in Figures 1-7, and in the claims as originally filed. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

**I. Interviews**

The courtesies extended to Applicants' representative by Examiner Polansky and Examiner Marschel at the personal interview held March 3, 2009 and the follow-up telephone interview held March 10, 2009, are appreciated. The reasons presented at the interviews as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interviews.

**II. Rejection Under Written Description Requirement**

The Office Action rejects claims 1, 3, 8, 9, 14-20, 28, and 37 under the written description requirement of 35 U.S.C. §112, first paragraph. By this Amendment, claim 14 is canceled, rendering its rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

By this Amendment, independent claims 1, 3, 8, 9, 20, and 37 are amended to recite "β-aminoisobutyric acid, an organic or inorganic salt thereof, or an ester thereof" instead of "β-aminoisobutyric acid, derivative, prodrug, metabolite or complex thereof." Support for the amendments may be found, for example, in the specification at page 6, line 30 to page 7, line

2. During the interviews, the Examiners indicated that at least "an organic or inorganic salt" of  $\beta$ -aminoisobutyric acid is supported by Applicants' disclosure.

Esters of  $\beta$ -aminoisobutyric acid are likewise supported by Applicants' disclosure. To provide written description for a claim, the specification as originally filed must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicants were in possession of the invention as claimed. See MPEP §2163(I). Applicants respectfully submit that one of ordinary skill in the art would readily envision esters of  $\beta$ -aminoisobutyric acid that could be used to practice the claimed methods because such chemical modifications are routine in the art. That is, one of ordinary skill in the art would readily recognize which esters of  $\beta$ -aminoisobutyric would generate  $\beta$ -aminoisobutyric as an active agent and therefore be suitable for use in the claimed methods. Accordingly, all that is required is an indication that esters of  $\beta$ -aminoisobutyric acid were contemplated by the inventors to convey with reasonable clarity to one of ordinary skill in the art that the Applicants were in possession of the same.

By this Amendment, claims 38-43 are added, which depend from claims 1, 3, 8, 9, 20, and 37, respectively, and further require that "the ester is a lower alkyl ester." During the interviews, the Examiners indicated that a lower alkyl ester should be supported by Applicants' disclosure. Prompt examination and allowance of new claims 38-43 are respectfully requested.

By this Amendment, claims 1 and 20 are amended to be directed to "A method for reducing the accumulation of triglycerides in tissues and blood." Accordingly, claims 1 and 20 are no longer directed "diseases linked to the accumulation of triglycerides" (emphasis added). During the interviews, the Examiners indicated that amending claims 1 and 20 to be directed to methods for reducing the accumulation of triglycerides should overcome this aspect of the rejection.

For at least the above reasons, claims 1, 3, 8, 9, 20, and 37 meet the written description requirement of 35 U.S.C. §112, first paragraph. Claims 15-19 and 28 variously depend from claims 1 and 20 and thus also meet the written description requirement.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

### **III. Rejection Under Enablement Requirement**

The Office Action rejects claims 1, 8, 14-19, 20, and 28 under the enablement requirement of 35 U.S.C. §112, first paragraph. By this Amendment, claim 14 is canceled, rendering its rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

#### **A. Independent Claims 1 and 20**

By this Amendment, claims 1 and 20 are amended to be directed to "A method for reducing the accumulation of triglycerides in tissues and blood." Accordingly, the claimed methods are no longer directed to "the prevention of diseases linked to the accumulation of triglycerides in tissues and blood." During the interviews, the Examiners indicated that amending claims 1 and 20 to be directed to methods for reducing the accumulation of triglycerides should overcome this aspect of the rejection.

#### **B. Independent Claim 8**

By this Amendment, claim 8 is amended to be directed to "A method for treating or reducing the risk of developing an obese condition" (emphasis added). Support for the amendments to claim 8 may be found, for example, in the specification at page 3, lines 26-31, pages 16-19 (Example 1) and in Figures 1-3. During the interviews, the Examiners indicated that the claim term "prevention" is being construed to require a substantial amount of prevention, but something less than 100% prevention. It was agreed that the claim feature of "reducing the risk of developing an obese condition" should overcome this aspect of the rejection.

**C. Conclusion**

For at least the above reasons, claims 1, 8 and 20 meet the enablement requirement of 35 U.S.C. §112, first paragraph. Claims 15-19 and 28 variously depend from claims 1 and 20 and thus also meet the enablement requirement. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**IV. Rejection Under 35 U.S.C. §103**

The Office Action rejects claims 1, 3, 8, 9, 14-20, and 28 under 35 U.S.C. §103(a) as allegedly obvious over the combination of U.S. Patent No. 5,457,114 to Stuber et al. ("Stuber") and "The Merck Manual," 17<sup>th</sup> Edition, 1999, pages 918-920 and 1654-1658 ("The Merck Manual"). By this Amendment, claim 14 is canceled, rendering its rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

By this Amendment, independent claims 1, 3, 8, 9, and 20 are amended to require "β-aminoisobutyric acid, an organic or inorganic salt thereof, or an ester thereof." The combination of applied references fails to teach or suggest or establish any reason or rationale to provide or use β-aminoisobutyric acid itself, or any salts or esters thereof. During the interviews, the Examiners agreed that the combination of Stuber and The Merck Manual failed to render obvious β-aminoisobutyric acid itself, or any salts or esters thereof.

Accordingly, the combination of Stuber and The Merck Manual would not have rendered obvious claims 1, 3, 8, 9, and 20. Claims 15-19 and 28 variously depend from claims 1 and 20 and thus also would not have been rendered obvious by the combination of Stuber and The Merck Manual for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

**V. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of this application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachment:

Petition for Extension of Time

Date: April 6, 2009

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